

## **REMARKS**

### **Claim Rejections – 35 USC § 103**

Claims 1, 2, 6-10, 13-15, 17, 18, 20, 52, 54, 56, 59, 61-64, 66-68 and 75 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,593,409 to Michelson.

### **Non-Examined Claims 83-92**

As an initial matter, the Applicant notes that the current Office Action does not address claims 83-92 which were added to the subject application in the response filed with the U.S. Patent and Trademark Office on January 8, 2008. Indeed, the Office Action Summary page does not even acknowledge that claims 83-92 are pending in the current application, and the Office Action does not in any way address the subject matter recited in claims 83-92. Since claims 83-92 have not been examined in the current Office Action, the Applicant requests issuance of a Notice of Allowance, or alternatively that finality of the current Office Action be removed followed by the issuance of a non-final Office Action which addresses the patentability of each of the pending claims, including non-examined claims 83-92.

### **Independent Claims 1, 13 and 52**

Independent claims 1, 13 and 52 have been rejected as being unpatentable over Michelson. The Office Action indicates that Michelson does not disclose “that the opening in the side wall discontinuity could extend over at least about 50% of the length and at least 20% of the circumference” of the implant body. Nevertheless, the Office Action asserts that it would have been obvious to provide an opening having such features “since Michelson explicitly discloses that the opening(s) may have ‘ANY shape, size or form’.” (See pages 2-3 of the Office Action; emphasis in original). The Applicant notes that the rejection of independent claims 1, 13 and 52 as being unpatentable over Michelson is based solely on the general statement that “the openings 128 may have any . . . size”.

Although Michelson states that the openings 128 may have “any shape, size or form”, such statement is non-specific and very general in nature. Indeed, the bone ingrowth openings 128 are smaller than those called for in independent claims 1, 13 and 52, and although the size of

the openings 128 may be increased to some extent, one of ordinary skill in the art would not be led by the Michelson disclosure to increase the size of one such bone ingrowth opening 128 to the extent required by the present claims “to extend over at least about 20% of the outer circumference of said body and along at least about 50% of the length of said body” based solely on the general statement that “the openings 128 may have any . . . size”. Moreover, the purpose of the openings 128 is to allow for bone ingrowth into the internal chamber 114 (see col. 10, ll. 8-12), and Michelson does not disclose the use or configuration of these openings 128 to “allow for loading osteogenic material into said interior chamber”, as recited in independent claims 1, 13 and 52. Instead, the Michelson disclosure discusses the provision of a large opening extending through the end of the implant to allow for loading of bone growth material into the hollow interior of the implant.

Moreover, in addition to being provided with a large side wall opening for loading osteogenic material into the interior chamber, the implant recited in independent claims 1, 13 and 52 is also provided with “a plurality of secondary bone ingrowth openings extending through said outer circumferential surface” and communicating with the interior chamber to facilitate bone ingrowth into the interior chamber. These secondary bone ingrowth openings are configured to allow for bone ingrowth into the implant and are specifically recited as being “sized smaller than said side wall opening”, with the side wall opening defined by the side wall discontinuity. The Applicant notes that Michelson does not disclose these additional features. Referring to Figures 23, 31, 36 and 42 of Michelson, even assuming arguendo that any of the small openings extending through the flat wall portions could be construed as “a side wall opening” defined by a side wall discontinuity, the openings 428, 528, 628 and 829 extending through the circumferential surface of the arcuate wall portions are not “sized smaller than said side wall opening”. To the contrary, the openings 428, 528, 628 and 829 defined by the arcuate wall portions (which have apparently been construed as the portions of the implant wall defining an outer circumferential surface) are sized larger than the openings extending through the flat wall portions (which have apparently been construed as a side wall discontinuity).

Once more, although Michelson discloses that “the openings 128 may have any shape, size or form”, there is no indication that the openings 428, 528, 628 and 829 extending through

the arcuate wall portions are “sized smaller than” the openings extending through the flat side walls. Furthermore, the Applicant notes that the Office Action does not set forth any bases or grounds as to how Michelson discloses or suggests “a plurality of secondary bone ingrowth openings extending through said outer circumferential surface” that are “sized smaller than said side wall opening” defined by the side wall discontinuity. Additionally, independent claim 52 recites that the generally cylindrical body has “external threads”. Once again, the Applicant notes that the Office Action does not set forth any bases or grounds as to how Michelson discloses or suggests an elongate spacer body having external threads. The Applicant further notes that Michelson discloses that the implant is provided with ratchetings so that the implant “may be pushed into the cylindrical disc space D by direct linear advancement since it requires no thread to pull it forward through the spine.” (See column 9, lines 16-19). Accordingly, a *prima facie* case of obviousness has not been established with regard to independent claims 1, 13 and 52.

For at least the reasons set forth above, the Applicant submits that independent claims 1, 13 and 52 are patentable over Michelson. Accordingly, the Applicant respectfully requests withdrawal of the rejection of independent claims 1, 13 and 52 and allowance of the same.

**Rewritten Independent Claims 83 and 91**

As indicated above, the current Office Action does not in any way address the subject matter recited in claims 83-92 which were added to the subject application in the response filed with the U.S. Patent and Trademark Office on January 8, 2008. The Applicant has chosen to rewrite non-examined claims 83 and 91 in independent form.

Rewritten independent claims 83 and 91 recite each of the elements and features recited in independent claims 1 and 52, respectively, and are therefore submitted to be patentable for at least the reasons set forth above in support of the patentability of independent base claims 1 and 52. Additionally, rewritten independent claims 83 and 91 further recite that “said end walls are fixed and non-removable relative to said elongated body”. With regard to Michelson, although one end of the fusion implant is closed off by an end wall, the opposite end is disclosed as open to allow for the loading of a fusion enhancing material. (Col. 10, lines 25-29). The open end

does not, therefore, cooperate with the side wall to define the hollow interior. Additionally, although Michelson discloses that the open end may be closed off via an end cap (col. 10, lines 25-27), the end cap is not disclosed as being “fixed and non-removable” relative to the implant body, as recited in independent claims 83 and 91. Instead, the end cap is disclosed as non-fixedly and removably coupled to the open end of the implant.

As indicated above, since the implant body of the claimed invention defines a large side wall opening that is sized to provide access to the hollow interior to accommodate loading of a bone growth material therein, the end walls which enclose the hollow interior may be “fixed and non-removable” relative to the implant body. (See page 9, lines 8-13; page 12, lines 7-10; page 18, lines 28-29). Additionally, the size of the side wall opening can be quite large without compromising the structural integrity of the implant body since each of the end walls are formed integral with and are fixed and non-removable relative to the implant body to provide resistance to loading exerted onto the implant body by the adjacent vertebrae. With regard to Michelson, there is no teaching that the implant includes first and second end walls that are “fixed and non-removable” relative to the implant body, for to do so would not provide access to the hollow interior to allow for the loading of fusion promoting material into the hollow interior.

For at least the reasons set forth above, the Applicant submits that rewritten independent claims 83 and 91 are patentable over Michelson. Accordingly, the Applicant respectfully requests allowance of independent claims 83 and 91.

**Dependent Claims 2, 6-10, 14, 15, 17, 18, 20, 54, 56, 59, 61-64, 66-68, 75, 84-90 and 92-95**

Claims 2, 6-10, 14, 15, 17, 18, 20, 54, 56, 59, 61-64, 66-68, 75, 84-90 and 82-95 depend either directly or indirectly from independent claims 1, 13 and 52, and are submitted to be patentable for at least the reasons supporting the patentability of their respective independent claims. However, further reasons support the patentability of the claims depending from independent claims 1, 13 and 52.

For example, dependent claims 59 and 62 each recite that “said outer circumferential surface defines threaded bone engaging portions”. However, as indicated above with regard to independent claim 52, the Office Action does not set forth any bases or grounds as to how the

invention disclosed in Michelson includes an elongate spacer body having external threads or “threaded bone engaging portions”, as recited in dependent claims 59 and 62.

Additionally, dependent claim 64 has been amended to recite that the first and second end walls are formed integral with the side wall, and that “said first and second end walls are fixed and non-removable relative to said elongated body”. As indicated above with regard to rewritten independent claims 83 and 91, Michelson does not disclose or suggest such features.

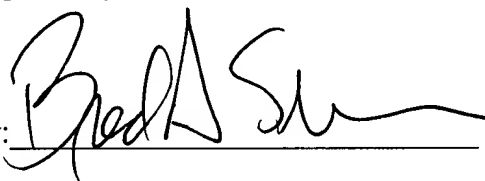
Furthermore, dependent claims 85, 88 and 92 each recite that “said side wall opening is sized to extend along at least about 80% of the length of said body”, and dependent claims 93, 94 and 95 further recite that “said side wall opening is sized to extend along substantially the entire length of said body”. (See Figures 1 and 3 of the as-filed application where the side wall opening 1160 extends substantially entirely along the length *L* of the implant body). As indicated above, the bone ingrowth openings 128 of Michelson are smaller than those required in the present claims, and although the size of the openings 128 may be increased to some extent, one of ordinary skill in the art would not be led to increase the size of one such bone ingrowth opening 128 so as to extend along “at least about 80% of the length of said body” or along “substantially the entire length of said body” based solely on the general statement that “the openings 128 may have any . . . size”.

## CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the Applicant's application is now in condition for allowance with pending claims 1, 2, 6-10, 13-15, 17, 18, 20, 52, 54, 56, 59, 61-64, 66-68, 75 and 83-95.

Reconsideration of the subject application is respectfully requested. Timely action towards a Notice of Allowability is hereby solicited. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the subject application.

Respectfully submitted,

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